# TRANSPORTED lication of:

#### IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Art Unit: 1654

Examiner: C. Bradley

Hart et al.

Serial No.:

10/559,758

Filed:

March 3, 2006

Entitled:

PEPTIDES FOR TARGETING TO IMMATURE DENDRITIC

**CELLS** 

Attorney Docket No.: ABL-012.1P US

#### **Mail Stop Amendment**

Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450

# SUPPLEMENTAL INFORMATION DISCLOSURE **STATEMENT UNDER 37 CFR §§ 1.56, 1.97 AND 1.98**

Dear Sir:

In accordance with the duty of disclosure under 37 CFR § 1.56, Applicants submit this Supplemental Information Disclosure Statement pursuant to 37 CFR §§ 1.97 and 1.98 in the aboveidentified application for consideration by the Patent Office. This paper is filed pursuant to 37 CFR § 1.97(b)(3) before the mailing of a first Office Action on the merits. Accordingly, no fee is believed to be required.

# **Foreign Published Applications**

DE 198 45 251, published March 9, 2000, Schüsener, H. J.;

WO 91/18010, published November 28, 1991, Fecondo et al.;

WO 98/44121, published October 8, 1998, Legrand et al.;

WO 98/54347, published December 3, 1998, Hart et al.;

WO 01/58940, published August 16, 2001, Roelvink et al.;

WO 02/057445, published July 25, 2002, Muruganandam et al.;

WO 02/057447, published July 25, 2002, Beach et al.;

WO 02/072616, published September 19, 2002, Hart et al.;

WO 03/004646, published January 16, 2003, Byrne et al.;

WO 03/008537, published January 30, 2003, Simard et al.; and

# Foreign Published Applications (Continued)

WO 03/094974, published November 20, 2003, Hurley et al.

#### **Non-Patent Literature Documents**

Office Action, dated January 20, 2010, issued in European patent application No. 04 736 220.7;

Bachman et al., "Integrin receptor-targeted transfer peptides for efficient delivery of antisense oligodeoxynucleotides", *J. Mol. Med.*, 76(2): 126-132 (1998);

Bandyopadhyay, "Nucleotide exchange in genomic DNA of rat hepatocytes using RNA/DNA oligonucleotides. Targeted delivery of liposomes and polyethyleneimine to the asialoglycoprotein receptor", *J. Biol. Chem.*, 274(15): 10163-10172 (1999);

Bettinger et al., "Size reduction of galactosylated PEI/DNA complexes improves lectin-mediated gene transfer into hepaotcytes", *Bioconjugate Chem.* 10(4): 558-561 (1999);

Boer et al., "Design and synthesis of potent and selective alpha(4)beta(7) integrin antagonists", *J. Med. Chem.*, 44(16): 2586-2592 (2001);

Brandao et al., "CD40-targeted adenoviral gene transfer to dendritic cells through the use of a novel bispecific single-chain Fv antibody enhances cytotoxic T cell activation", *Vaccine*, 21(19-20): 2268-2272 (2003);

Boussif et al., "A versatile vector for gene and oligonucleotide transfer into cells in culture and in vivo: polyethylenimine", *Proc. Natl. Acad. Sci. USA*, 92(16): 7297-7301 (1995);

Castilho et al., "An integrated process for mammalian cell perfusion cultivation and product purification using a dynamic filter", *Biotechnol. Prog.*, 18(4): 776-781 (2002);

Chowdhury et al., "Fate of DNA targeted to the liver by asialoglycoprotein receptor-mediated endocytosis in vivo. Prolonged persistence in cytoplasmic vesicles after partial hepatectomy", *J. Biol. Chem.*, 268(15): 11265-11271 (1993);

Cole-Strauss et al., "Correction of the mutation responsible for sickle cell anemia by an RNA-DNA oligonucleotide", *Science*, 273(5280): 1386-1389 (1996);

Cruz et al., "Process development of a recombinant antibody/interleukin-2 fusion protein expressed in protein-free medium by BHK cells", *J. Biotechnol.*, 96(2): 169-183 (2002);

Curiel et al., "Adenovirus enhancement of transferring-polylysine-mediated gene delivery", *Proc. Natl. Acad. Sci. USA*, 88(19): 8850-8854 (1991);

Durocher et al., "High-level and high-throughput recombinant protein production by transient transfection of suspension-growing human 293-EBNA1 cells", *Nucleic Acids Res.*, 30(2): E9 (2002);

# **NPL Documents (Continued)**

Ehsan et al., "Long-term stabilization of vein graft wall architecture and prolonged resistance to experimental atherosclerosis after E2F decoy oligonucleotide gene therapy", *J. Thorac. Cardiovasc. Surg.*, 121(4): 714-722 (2001);

Ehsan et al., "Endothelial healing in vein grafts: proliferative burst unimpaired by genetic therapy of neointimal disease", Circulation, 105(14): 1686-1692 (2002);

Erbacher et al., "Gene transfer with synthetic virus-like particles via the integrin-mediated endocytosis pathway", Gene Therapy, 6(1): 138-145 (1999);

Felgner et al., "Nomenclature for synthetic gene delivery systems", *Hum. Gene Ther.*, 8(5): 511-512 (1997);

Goncz et al., "Targeted replacement of normal and mutant CFTR sequences in human airway epithelial cells using DNA fragments", *Hum. Mol. Genet.*, 7(12): 1913-1919 (1998);

Groth et al., "A phage integrase directs efficient site-specific integration in human cells", *Proc. Natl. Acad. Sci. USA*, 97(11): 5995-6000 (2000);

Han et al., "Receptor-mediated gene transfer to cells of hepatic origin by galactosylated albumin-polylysine complexes", *Biol. Pharm. Bull.*, 22(8): 836-840 (1999);

Ivanenkov et al., "Targeted delivery of multivalent phage display vectors into mammalian cells", Biochimica et Biophysica Acta, 1448(3): 463-472 (1999);

Knudsen et al., "Application of peptide nucleic acid in cancer therapy", Anti-cancer Drugs, 8(2): 113-118 (1997);

Kren et al., "In vivo site-directed mutagenesis of the factor IX gene by chimeric RNA/DNA oligonucleotides", *Nat. Med.*, 4(3): 285-290 (1998);

Krieg et al., "CpG motifs in bacterial DNA trigger direct B-cell activation", *Nature*, 374(6522): 546-549 (1995);

Mann et al., "Ex-vivo gene therapy of human vascular bypass grafts with E2F decoy: the PREVENT single-centre, randomized, controlled trial", *Lancet*, 354(9189): 1493-1498 (1999);

Mannion et al., "Sustained reduction of neointima with c-myc antisense oligonucleotides in saphenous vein grafts", Ann. Thorac. Surg., 66(6): 1948-1952 (1998);

Morishita et al., "A gene therapy strategy using a transcription factor decoy of the E2F binding site inhibits smooth muscle proliferation in vivo", *Proc. Natl. Acad. Sci. USA*, 92(13): 5855-5859 (1995);

Nicklin et al., "Ablating adenovirus type 5 fiber-CAR binding and HI loop insertion of the SIGYPLP peptide generate an endothelial cell-selective adenovirus", *Mol. Ther.*, 4(6): 534-542 (2001);

# **NPL Documents (Continued)**

Olivares et al., "Phage R4 integrase mediates site-specific integration in human cells", *Gene*, 278(1-2): 167-176 (2001);

Pereboev et al., "Coxsackievirus-adenovirus receptor genetically fused to anti-human CD40 scFv enhances adenoviral transduction of dendritic cells", *Gene Ther.*, 9(17): 1189-1193 (2002);

Reddy et al., "Optimization of folate-conjugated liposomal vectors for folate receptor-mediated gene therapy", J. Pharm. Sci., 88(11): 1112-1118 (1999);

Reddy et al., "Enhanced folate receptor mediated gene therapy using a novel pH-sensitive lipid formulation", *J. Controlled Release*, 64(1-3): 27-37 (2000);

Rosenkranz et al., "Receptor-mediated endocytosis and nuclear transport of a transfecting DNA contruct", Exp. Cell Res., 199(2): 323-329 (1992);

Shi Y., "Mammalian RNAi for the masses", Trends Genet., 19(1) 9-12 (2003);

Stoll et al., "Phage TP901-1 site-specific integrase functions in human cells", *J. Bacteriol.*, 184(13): 3657-3663 (2002);

Thyagarajan et al., "Mammalian genomes contain active recombinase recognition sites", *Gene*, 244(1-2): 47-54 (2000);

Thyagarajan et al., "Site-specific genomic integration in mammalian cells mediated by phage phiC31 integrase", Mol. Cell. Biol., 21(12): 3926-3934 (2001);

Tillman et al., "Maturation of dendritic cells accompanies high-efficiency gene transfer by a CD40-targeted adenoviral vector", *J. Immunol.*, 162(11): 6378-6383 (1999);

Wade-Martins et al., "Infectious delivery of a 135-kb LDLR genomic locus leads to regulated complementation of low-density lipoprotein receptor deficiency in human cells", *Molecular Therapy*, 7(5 Pt 1): 604-612 (2003);

Wang et al., "Increasing epithelial junction permeability enhances gene transfer to airway epithelia in vivo", Am. J. Respir. Cell Mol. Biol., 22(2): 129-138 (2000);

Watkins et al., "The 'adenobody' approach to viral targeting: specific and enhanced adenoviral gene delivery", *Gene Ther.*, 4(10): 1004-1012 (1997);

Wickham et al., "Targeting endothelium for gene therapy via receptors up-regulated during angiogenesis and inflammation", *Cancer Immunol. Immunother.*, 45(3-4): 149-151 (1997);

Woolf et al., "Toward the therapeutic editing of mutated RNA sequences", *Proc. Natl. Acad. Sci. USA*, 92(18): 8298-8302 (1995);

Wu et al., "Receptor-mediated in vitro gene transformation by a soluble DNA carrier system", *J. Biol. Chem.*, 262(10): 4429-4432 (1987);

# NPL Documents (Continued)

Wu et al., "Receptor-mediated gene delivery in vivo. Partial correction of genetic analbuminemia in Nagase rats", J. Biol. Chem., 266(22): 14338-14342 (1991);

Yano et al., "Improved gene transfer to neuroblastoma cells by a monoclonal antibody targeting RET, a receptor tyrosine kinase", *Hum. Gene Ther.*, 11(7): 995-1004 (2000);

Yant et al., "Somatic integration and long-term transgene expression in normal and haemophilic mice using a DNA transposon system", Nat. Genet., 25(1): 35-41 (2000); and

Yoon et al., "Targeted gene correction of episomal DNA in mammalian cells mediated by a chimeric RNA. DNA oligonucleotide", *Proc. Natl. Acad. Sci. USA*, 93(5): 2071-2076 (1996).

# **REMARKS**

On January 28, 2010, the Examiner issued an Examiner-Initiated Interview Summary that included a request to file a new IDS that further includes the titles of the articles from the NPL documents that had been listed in the first IDS submitted by Applicants on December 13, 2006. In compliance with the Examiner's request, Applicants submit herewith a Supplemental IDS with the titles of the articles from all NPL documents listed therein.

Also submitted herewith is a communication pursuant to Article 94(3) EPC issued by the European Patent Office in the European counterpart of the present application as well as any references cited in the Communication which have not previously been provided to the United States Patent Office in the present application.

Applicants do not intend to represent that any of the documents submitted herein is material prior art to this invention or that the list represents an exhaustive search of documents related to this invention.

Applicants respectfully request that the documents submitted herein be considered and made of record in this application, and also printed on any patent issuing from the above-identified application.

Respectfully submitted,

David G. O'Brien, Reg. No. 46,125 Leon R. Yankwich, Reg. No. 30,237

Attorneys for Applicants

YANKWICH & ASSOCIATES, P.C.

201 Broadway

Cambridge, Massachusetts 02139

telephone: (617) 374-3700 telefax: (617) 374-0055

# **Certificate of Mailing**

The undersigned hereby certifies that this correspondence and accompanying documents are being deposited with the United States Postal Service as First Class Mail, postage prepaid, in an envelope addressed to: Mail Stop Amendment, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on the date indicated below.

February 23, 2010

Date